## CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on March 30, 2004

Conchita Picako-Mejia

APR 0 2 2004

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Leonard KATZ et al.

Serial No.:

10/690,949

Filing Date:

October 21, 2003

For:

RECOMBINANT STREPTOMYCES

HYGROSCOPICUS HOST CELLS THAT

PRODUCE 17-

**DESMETHYLRAPAMYCIN** 

Examiner: Not Yet Assigned

Group Art Unit: 1652

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Pursuant to the USPTO notice dated July 11, 2003, waiving the requirement under 37 C.F.R. §1.98 (a)(2)(i) to provide copies of U.S. Patents and U.S. Published Applications, a copy of reference number 7 is not submitted. A copy of reference number 15 is submitted herewith. However, copies of the remaining documents cited in the attached Form PTO-1449 were previously submitted in an Information Disclosure Statement and/or Office Action, directed to the related application Serial

Number 09/702,029, filed October 30, 2000 (now U.S. Patent No. 6,670,168,) and, accordingly, copies are not included herewith. This protocol conforms with 37 C.F.R. §1.98(d) and M.P.E.P. 609(A)(2). The Examiner is requested to make this document of record in the application.

	This I	nformation Disclosure Statement is submitted:				
	With t	he application; accordingly, no fee or separate requirements are required.				
	Before the mailing of a first Office Action after the filing of a Request for Continued					
	Exami	nation under § 1.114. However, if applicable, a certification under 37 C.F.R. §				
	1.97(e	)(1) has been provided.				
$\boxtimes$	Withir	three months of the application filing date or before mailing of a first Office				
	Action	on the merits; accordingly, no fee or separate requirements are required.				
	Howe	ver, if applicable, a certification under 37 C.F.R. § 1.97(e)(1) has been provided.				
	After 1	receipt of a first Office Action on the merits but before mailing of a final Office				
	Action or Notice of Allowance.					
		A fee is required. A check in the amount of is enclosed.				
		A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached				
		to this submission in duplicate.				
		A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee				
		is believed to be due.				
	After	nailing of a final Office Action or Notice of Allowance, but before payment of the				
	issue fee.					
		A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the				
		amount of is enclosed.				
		A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal				
		form (PTO/SB/17 is attached to this submission in duplicate.)				

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does

not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no.300622005001. However, the Commissioner is not authorized to charge the cost of the issue

Dated:

fee to the Deposit Account.

March 30, 2004

Respectfully submitted,

Bv:

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PTO/SB/21 (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Onder the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. **Application Number** 10/690.949 Filing Date **TRANSMITTAL** October 21, 2003 First Named Inventor **FORM** Leonard KATZ Art Unit 1652 (to be used for all correspondence after initial filing) **Examiner Name** Not Yet Assigned Attorney Docket Number 8+1 Total Number of Pages in This Submission 300622005001 Reference ENCLOSURES (Check all that apply) After Allowance Communication Fee Transmittal Form Drawing(s) to Group Appeal Communication to Board of Fee Attached Licensing-related Papers Appeals and Interferences Appeal Communication to Group Amendment/Reply Petition (Appeal Notice, Brief, Reply Brief) Petition to Convert to a After Final **Proprietary Information** Provisional Application Power of Attorney, Revocation Affidavits/declaration(s) Status Letter Change of Correspondence Address Other Enclosure(s) (please Extension of Time Request Terminal Disclaimer identify below): Form PTO-1449 + copy (4 pages) Express Abandonment Request Request for Refund One (1) reference Return receipt postcard Information Disclosure Statement CD, Number of CD(s) (3 pages) Certified Copy of Priority Document(s) Remarks Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm MORRISON & FOERSTER LLP (Customer No. 25226) Randolph Ted Apple - 36,429 Individual name Signature Date March 30, 2004 I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below. Signature bushing Dated: March 30, 2004 (Conchita Picazo-Mejia)

Form PTO-1449					Docket Number 300622005001		Application Number 10/690,949		
INFORMATION DISCLOSURE CITATION IN AN APPLICATION					Applicant  Leonard KATZ et al.				
	(U	se several sheets if i	necessary)	Filing Date October 21, 2003 Group Art Unit 1652					
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Examiner Initials	Ref. No.	Date TAA	ocument No.		Name	Class	Subclass		Date If opriate
	1.	09/30/1997	5,672,491	Kho	sla et al.				
	2.	10/20/1998	5,824,513	Katz	z et al.				
	3.	10/05/1999	5,962,290	Kho	sla et al.				
	4.	05/23/2000	6,066,721	Kho	sla et al.				
	5.	06/27/2000	6,080,555	Kho	sla et al.				
	6.	03/13/2001	6,200,813	Katz	z et al.				
	7.	12/30/2003	6,670,168	Katz	z et al.				
FOREIGN PATENT DOCUMENTS  Examiner Ref. Date Document No. Country Class Subclass Translation									lation
Initials	No.							YES	NO
	8.	10/28/1992	EP 0 510 904	Euro	оре				
	9.	08/19/1993	WO 93/16189	WIF	О				
	10.	08/31/1995	WO 95/22972	WIF	О				
	11.	01/15/1998	WO 98/01546	WIF	<u> </u>			-	!
	12.	11/05/1998	WO 98/49315	WIF	О				
	13.	12/03/1998	WO 98/54308	WIF	О				
	14.	04/13/2000	WO 00/20601	WIF	0				
	15.	05/17/2001	WO 01/34816	WIF	0				
-			OTHER DOCUME	ENTS	(including author, titl	le, Date, Pertinent P	ages, Etc.)		
Examiner Initials	Ref. No.	Title							
	Aparicio, J.T. et al. (1996). "Organization of the Biosynthetic Gene Cluster for Rapamycin in Streptomyces Hygroscopicus: Analysis of the Enzymatic Domains in the Modular Polyketide Synthase," <i>Gene</i> 169:9-16.								
EXAMI	VER:			DATE CONSIDERED:					
EXAMIN	ER: Initia		idered, whether or not the		n conforms with MF	PEP 609. Draw a	line through the c	itation if no	ot in

			PTO/SB/08 (2-92) Sheet 2 of 2				
Form PTO-1449		Docket Number 300622005001	Application Number 10/690,949				
	ON DISCLOSURE CITATION AN APPLICATION	Applicant  Leonard KATZ et al.					
	e several sheets if necessary) APR 0 2 2004	Filing Date October 21, 2003	Group Art Unit 1652				
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	MIDEMAN						
17.	Lomovskaya et al. (1997). "Gene Disri Streptomyces Hygroscopicus Strain A'						
18.	Nelson, F.C. et al. (1999). "Manipulati and Biological Implications," <i>Bioorgan</i>	on of the C(922) - C(27) Region nic & Medicinal Chemistry Lett	n of Rapamycin: Stability Issues ers, 9(2):295-300.				
19.	Ruan, X. et al. (1997). "A Second Type-I PKS Cluster Isolated From Streptomyces Hygroscopicus ATCC 29253, a Rapamycin-Producing Strain," <i>Gene</i> 203:1-9.						
20.	Schwecke, T. et al. (1995). "The Biosynthetic Gene Cluster for the Polyketide Immunosuppressant Rapamycin," <i>Proc. Natl. Acad. Sci. USA</i> 92:7839-7843.						

**EXAMINER:** 

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.